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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,725	10/06/2000	Lee Harland	PCS10361ADAM	1550

7590  
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06/10/2002

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/684,725

Applicant(s)

HARLAND, LEE

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-12 and 22-36 is/are pending in the application.
- 4a) Of the above claim(s) 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-12 and 22-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2000 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **I. Election/Restrictions**

Applicants' election without traverse of Group I, Claims 1-12 and 22, in Paper No. 9 is acknowledged.

### **II. Status of Application, Amendments, and/or Claims**

The amendment filed in Paper No. 9 on May 7, 2002 has been entered in full. Claims 1-5 and 13-21 have been canceled. Claims 6-10 and 22 have been amended. Claims 23-36 have been added. Claims 6-12 and 22-36 remain pending. Claims 6-12 and 22-34 are under consideration. Claims 35 and 36 are withdrawn from further consideration because they are drawn to unelected subject matter.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **III. Withdrawn Objections and/or Rejections**

The objection to the title of the invention, as set forth at page 5 of the previous Office Action (Paper No. 8, November 2, 2001) has been withdrawn in view of applicants' amendment.

The rejection of Claims 1-5 under 35 U.S.C. 101 and 35 U.S.C. 112, 1<sup>st</sup> paragraph (item No. 14 and 15) for enablement, as set forth at pages 6-10 of the

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previous Office Action (Paper No. 8, November 2, 2001), has been withdrawn in view of applicants' cancellation of claims 1-5.

The rejection of Claims 1-5, 10, and 22 under 35 U.S.C. 101 and 35 U.S.C. 112, 1<sup>st</sup> paragraph (item No. 17) for written description, as set forth at pages 10-12 of the previous Office Action (Paper No. 8, November 2, 2001), has been withdrawn in view of applicants' cancellation of claims 1-5 and amendment of Claim 10.

The rejection of Claims 1, 8, and 22 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as set forth at pages 12-13 of the previous Office Action (Paper No. 8, November 2, 2001), has been withdrawn in view of applicants' claim amendment and cancellation.

The rejection of Claims 1-5, 8, 10, and 22 under 35 U.S.C. 102 (b), as set forth at page 13 (item No. 22) of the previous Office Action (Paper No. 8, November 2, 2001), has been withdrawn in view of applicants' argument, amendment of Claim 8, 10, and 22, and cancellation of Claims 1-5.

The rejection of Claim 1 under 35 U.S.C. 102 (b), as set forth at page 14 (item No. 23) of the previous Office Action (Paper No. 8, November 2, 2001), has been withdrawn in view of applicants' cancellation of the claim.

The rejection of Claim 8 under 35 U.S.C. 102 (b), as set forth at page 14 (item No. 24) of the previous Office Action (Paper No. 8, November 2, 2001), has been withdrawn in view of applicants' argument and claim amendment.

#### **IV. 35 U.S.C. § 101**

The rejection of Claims 6-12 and 22 under 35 U.S.C. 101 (Item No. 14), as set forth at pages 6-7 of the previous Office Action (Paper No. 8, November 2, 2001), remains.

New claims 23-34 are also rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well-established utility. The basis for this rejection is set forth at pages 6-7 of the previous Office Action (Paper No. 8, November 2, 2001).

The applicants argue that the disclosure teaches the use of hybridization techniques and probes complementary to PFI-002 (page 8, 4<sup>th</sup> paragraph) and that screening test samples for a DNA target would indeed be a real world and practice use of the claimed sequences (page 8, 4<sup>th</sup> paragraph). This has been fully considered but is not deemed to be persuasive because the use of probes complementary to PFI-002 is considered as research use only designed to identify a particular function of the claimed molecules and is not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." Moreover, such a use is not specific to the instant molecule but applicable to other nucleic acid molecules as well.

Likewise, production of antibody against PFI-002, screening test samples for a DNA target, and uses of antibodies for immunochemical methods are also considered as research utilities and do not provide the claimed molecule a specific and substantial utility in the instant case where there are no specific biological functions or activities of the claimed molecules disclosed.

The applicants argue that the present invention are directed in part to nucleic acid sequences, which encode polypeptides, and protein sequences belonging to the class of G-protein coupled receptors (GPCRs; page 8 last paragraph-page 9, 1<sup>st</sup> paragraph). This has been fully considered but is not deemed to be persuasive for the following reasons.

35 USC §101 requires disclosure of a specific, substantial, and credible utility. Such a patentable utility has to be a “real world “ context of use which does not require significant further research. The instant disclosure asserts that the deduced amino acid sequence encoded by the claimed nucleic acid is related to GPCRs. In view of the diversity of structure and functions of the proteins, prediction of function using comparative sequence analysis may lead to the creation and propagation of assignment errors if not performed appropriately (See, Peer Bork and Eugene V. Koonin, Predicting functions from protein sequences--where are the bottlenecks? *Nature Genetics* 18:313-318,1998), in particular when the degree of homology is low. There are putative seven transmembrane molecules, which do not appear to be coupled to a G protein (Ji et al. G-protein-coupled receptors, *J. Biol. Chem.*, 273:17299-17302, 1998).

The information provided or “predicted” based upon sequence homology can only be used as guidance in determining functions or activities of a molecule by experiments. Any functions predicted based upon the sequence homology will have to be confirmed ultimately by bench work. Such confirmation whether the claimed nucleic acid encodes a GPCR molecule requires undue experimentation. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that “a patent is not a

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hunting license. It is not a reward for the search, but compensation for its successful conclusion."

In summary, the disclosure fails to provide a specific, substantial, and credible utility, or a well-established utility.

#### **V. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph**

The rejection of Claims 6-12 and 22 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph (item No. 14 and 15), as set forth at pages 7-10 of the previous Office Action (Paper No. 8, November 2, 2001), remains.

New claims 23-34 are also rejected under 35 U. S. C. § 112, 1<sup>st</sup> paragraph. The basis for this rejection is set forth at pages 6-7 of the previous Office Action (Paper No. 8, November 2, 2001). Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention.

The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reasons set above.

#### **VI. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> paragraph, Written Description**

The rejection of Claims 6-9 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph, written description (item No. 17), as set forth at page 10-12 of the previous Office Action (Paper No. 8, November 2, 2001), remains.

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New claims 23, 29, 31, and 34 are also rejected under 35 U. S. C. § 112, 1<sup>st</sup> paragraph, written description. The basis for this rejection is set forth at pages 6-7 of the previous Office Action (Paper No. 8, November 2, 2001).

The applicants' arguments has been fully considered but is not deemed to be persuasive for reasons set above and for the following reasons.

The Criteria to determine whether a disclosure satisfies the requirement under 35 U. S. C. § 112, 1<sup>st</sup> paragraph enablement and written description are different. The Wands factors are used to determine enablement whereas the following factors are used to determine a disclosure satisfies written description: (1) complete or partial structure; (2) physical and /or chemical properties; (3) functional characteristics; (4) correlation between structure and function; (5) method of making; (6) combinations of the above. Thus, applicants' argument based upon enablement is irrelevant to the claim rejection under U. S. C. § 112, 1<sup>st</sup> paragraph, written description.

## **VII. Claim Rejections under 35 U.S.C. § 102 (b)**

The rejection of Claims 6, 7, and 9 under 35 U.S.C. 102 (b), as set forth at page 13 (item 22) of the previous Office Action (Paper No. 8, November 2, 2001), remains. The new claims 23-27, 31, and 34 are also rejected under 35 U.S.C. 102(b) on the same basis.

Claims 6, 7, 9, 23-27, 31, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Database EMBL Accession No. AC008571 (August 3, 1999), which discloses a nucleotide sequence comprising SEQ ID NO: 1, that encodes a G-protein



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coupled receptor. The nucleotide sequence is present in a cloning vector, meeting the limitation of claims 6, 7, 9, 23-27, 31, and 34.

The applicants argue that the EMBL sequence listing is drawn to a genomic sequence of 216 kb and was replaced on May 5, 2000. This has been fully considered but is not deemed to be persuasive for the following reasons. The claims recite an isolated or purified polynucleotides, it reads on both cDNA and genomic sequences. While the EMBL sequence has been updated, the updated version still comprises 100% of SEQ ID NO: 1 (See attached sequence alignment).

The rejection of Claims 7, 9-12 and 22 under 35 U.S.C. 102 (b), as set forth at page 14 (item 24) of the previous Office Action (Paper No. 8, November 2, 2001), remains. The new claims 23, 29, 31, and 34 are also rejected under 35 U.S.C. 102(b) on the same basis.

The applicants argue that the reference by Tan et al. does not meet the claim limitations. This has been fully considered but is not deemed to be persuasive for the reasons set forth in the previous Office Action (Paper No. 8, November 2, 2001).

The rejection of Claim 12 under 35 U.S.C. 102 (b), as set forth at page 14 (item 25) of the previous Office Action (Paper No. 8, November 2, 2001), remains.

The applicants argue that the reference by Maniatis et al. does not anticipate the subject matter of Claim 12. This has been fully considered but is not deemed to be persuasive for the following reasons, as well as for the reasons set forth in the previous Office Action (Paper No. 8, November 2, 2001).

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Claim 12 recites a membrane preparation of a host cell of claim 10. The examiner understands that applicants intend to recite a membrane comprising a polypeptide of SEQ ID NO: 2 encoded by SEQ ID NO: 1. However, It should be noted that the polypeptide is present in the exclusion bodies, not in the membrane, if a yeast cell is used as the host cell. Thus, the claim, as written, encompasses a membrane preparation comprising the polypeptide as well as a membrane preparation without the polypeptide.

#### **VIII. Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
June 3, 2002



ELIZABETH KEMMERER  
PRIMARY EXAMINER